



1 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of ]  
Troy M. Just ]  
Serial No.: 10/668,785 ]  
Filed: September 23, 2003 ]  
Title: PRE-FILL APPLICATOR ]  
Group No.: 3761 ]  
5 BEFORE THE BOARD  
OF PATENT APPEALS  
AND INTERFERENCES  
Appeal No. \_\_\_\_\_

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APPELLANT'S THIRD AMENDED APPEAL BRIEF  
Commissioner for Patents  
Alexandria, VA 22313

15 Dear Sir:

REAL PARTY IN INTEREST

The Appellant has assigned all of his rights to the invention herein to HTI Plastics; therefore, the real party in interest is HTI Plastics, Lincoln, Nebraska 68524.

RELATED APPEALS AND INTERFERENCES

20 There are no appeals or interferences related to this case.

STATUS OF THE CLAIMS

This is an appeal of the Examiner's final rejection of claims 1-3, 8, 10 and 11. Claim 1 is an independent claim with claims 2 and 3 depending therefrom. Claim 8 is

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1 an independent claim with claims 10 and 11 depending therefrom. Claims 1-3, 8, 10  
and 11 are being appealed. Claims 4-7, 9 and 12-16 have been cancelled.

#### STATUS OF AMENDMENTS

5 The Examiner entered a final rejection of Appellant's claims on May 19, 2006.  
Appellant did not file an Amendment After Final Rejection.

#### SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 describes a pre-fill vaginal applicator 10 (Fig. 2; p. 6, line 1) including a tubular barrel 16 (Fig. 9; p. 1, lines 3-8) having a dispensing end 20 (Fig. 9) provided with at least one opening formed therein and an open end 22 (Fig. 10). A selectively removable closure 12 (Figs. 2, 12, 13) or 14 (Figs. 19, 20; p. 6, lines 3-6) closes the dispensing end of the barrel when the applicator is not being used. A resilient piston 62 (Figs. 3-5, 14, 15; p. 7, lines 18-22) is selectively slidably positioned in the barrel 16 with the piston 62 having an outer surface which is in 15 sealing contact with the inner surface of the barrel 16 (Figs. 14, 15) to define a medication reservoir 78 (Fig. 15; p. 8, lines 16-20). The second end of the piston has an opening 68 (Fig. 3; p. 7, lines 21, 22, and p. 8, lines 1-5) extending thereinto 20 which terminates between the first and second ends of the piston 62. An elongated plunger 48 (Fig. 6; p. 7, lines 12-20) is inserted into the open end of the barrel with the first end of the plunger 48 being inserted into the opening 68 in the second end of the piston 62 to detachably connect the plunger to the piston (Figs. 14, 15; p. 9, lines 25 9-17). The piston 62, prior to insertion into the barrel 16, has a larger outside diameter than the inside diameter of the barrel 16 whereby the piston 62 is in a

1 compressed state against the inner surface of the barrel 16 when the piston 62 is  
2 inserted into the barrel 16 (p. 9, lines 9-17). The plunger 48, when connected to the  
3 piston 62 and moved towards the dispensing end of the barrel 16, causes the  
4 resilient piston 62 to longitudinally stretch to permit the piston 62 to slide towards the  
5 dispensing end of the barrel 16, thereby forcing medication in the medication  
6 reservoir 78 to be ejected from the opening in the dispensing end of the barrel (Fig.  
7 14; p. 9, lines 18-22, and p. 10, lines 1-7). The first end of the plunger 48 is  
8 detachably connected to the piston whereby movement of the plunger 48 away from  
9 the piston 62 will cause the first end of the plunger 48 to disconnect from the piston  
10 62 so that the piston 62 remains in the barrel, thereby ensuring that the applicator  
11 may not be reused (p. 9, lines 8-18).

12 Claim 2 depends from claim 1 and describes that the piston 62 has a portion  
13 thereof shaped so as to be receivable within the opening formed in the dispensing  
14 end of the barrel 16 (Figs. 3-5; p. 7, lines 21-22, and p. 8, lines 1-5).

15 Claim 3 is also dependent from claim 1 and describes that the piston 62 is  
16 constructed so as to destruct if an attempt is made to manually move the piston 62  
17 towards the open end of the barrel 16 by applying force against the first end thereof,  
18 thereby further ensuring that the applicator may not be reused (p. 10, lines 8-18).

19 Independent claim 8 describes a vaginal applicator 10 (Fig. 2; p. 6, line 1)  
20 including a tubular barrel 16 (Fig. 9; p. 1, lines 3-8) having a dispensing end 20 (Fig.  
21 9) provided with at least one opening formed therein and an open end 22 (Fig. 9). A  
22 resilient piston 62 (Figs. 3-5, 14, 15; p. 7, lines 18-22) is selectively slidably  
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1 positioned in the barrel 16 with the piston 62 having an outer surface which is in  
sealing contact with the inner surface of the barrel 16 (Figs. 14, 15) to define a  
medication reservoir 78 (Fig. 15; p. 8, lines 16-20). The second end of the piston has  
an opening 68 (Fig. 3; p. 7, lines 21, 22, and p. 8, lines 1-5) extending thereinto  
5 which terminates between the first and second ends of the piston 62. An elongated  
plunger 48 (Fig. 6; p. 7, lines 12-20) is inserted into the open end of the barrel with  
the first end of the plunger 48 being inserted into the opening 68 in the second end of  
the piston 62 to detachably connect the plunger to the piston (Figs. 14, 15; p. 9, lines  
10 9-17). The piston 62, prior to insertion into the barrel 16, has a larger outside  
diameter than the inside diameter of the barrel 16 whereby the piston 62 is in a  
compressed state against the inner surface of the barrel 16 when the piston 62 is  
inserted into the barrel 16 (p. 9, lines 9-17). The plunger 48, when connected to the  
piston 62 and moved towards the dispensing end of the barrel 16, causes the  
15 resilient piston 62 to longitudinally stretch to permit the piston 62 to slide towards the  
dispensing end of the barrel 16, thereby forcing medication in the medication  
reservoir 78 to be ejected from the opening in the dispensing end of the barrel (Fig.  
14; p. 9, lines 18-22, and p. 10, lines 1-7). The first end of the plunger 48 is  
20 detachably connected to the piston whereby movement of the plunger 48 away from  
the piston 62 will cause the first end of the plunger 48 to disconnect from the piston  
62 so that the piston 62 remains in the barrel, thereby ensuring that the applicator  
may not be reused (p. 9, lines 8-18).

1           Claim 10 depends from claim 8 and describes that the piston 62 has a portion  
thereof shaped so as to be receivable within the opening formed in the dispensing  
end of the barrel 16 (Figs. 3-5; p. 7, lines 21-22, and p. 8, lines 1-5).

5           Claim 11 is also dependent from claim 8 and describes that the piston 62 is  
constructed so as to destruct if an attempt is made to manually move the piston 62  
towards the open end of the barrel 16 by applying force against the first end thereof,  
thereby further ensuring that the applicator may not be reused (p. 10, lines 8-18).

10          It is believed that each of the claims are allowable and stand by themselves.

10          GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(A) Whether claims 1-3, 8, 10 and 11 are patentable over Ferrer et al. (U.S. Patent No. 6,364,854) under 35 U.S.C. § 103(a).

15          It is the Examiner's position with respect to claims 1 and 8 that Ferrer et al. ("Ferrer") teaches a vaginal medication applicator 10 having a piston 40 slidably mounted on a rod within the main body 20 which is therefore capable of being selectively positioned. It is the Examiner's position that piston 40 fits snugly within section 23 of the main applicator body and provides a closure to the compartment wherein medication is stored. The Examiner also believes that upon application of  
20         force to piston 40 by plunger 30, piston 40 is pushed along body 20 towards dispensing end 21 while being longitudinally stretched. The Examiner also believes that Ferrer teaches that the piston and plunger are an effectively unitary impeller means in that when the applicator is manufactured, the piston and plunger are assembled together in an engaged configuration and that therefore, when the  
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1 impeller means is advanced to propel medication out of the end of the applicator,  
both the piston and plunger remain in the barrel to ensure that the applicator is not  
reusable. The Examiner admits that Ferrer does not explicitly teach that the plunger,  
as it exists within an assembled applicator, is detachably connected to the piston in  
5 such a manner as to be capable of being disconnected from the piston, thereby  
leaving the piston in the main body portion. The Examiner has concluded that it  
would be obvious to one of ordinary skill in the art to modify the applicator of Ferrer to  
be manufactured separately from the piston in such a way as to allow the plunger to  
10 disconnect from the piston upon completion of use, as these pieces are  
manufactured separately and are capable of being assembled separately as an  
alternative means of assembling that produces a substantially identical product to the  
claimed invention.

15 With respect to claims 2 and 10, the Examiner contends that Ferrer teaches  
that the piston 40 fits snugly within portion 23 of body 20 and is thus receivable in  
openings 26.

20 With respect to claims 3 and 11, the Examiner contends that since Ferrer  
teaches that piston 40 and plunger 30 are assembled together and are constructed in  
a complementary manner such that plunger 30 having rib 34 and groove 35 engage  
piston 40 via orifice 45 to lock the piston 40 in place, forms an effectively unitary  
impeller structure. The Examiner concluded that application of a certain amount of  
force against the first end of the plunger 30 that is disposed within orifice 45 of piston

40 will result in the destruction of the impeller system, thus ensuring that the applicator cannot be reused.

## ARGUMENT

(A) Whether claims 1-3, 8, 10 and 11 are patentable over Ferrer et al. (U.S. Patent No. 6,364,854) under 35 U.S.C. § 103(a).

Appellant does not contend that he is the first person to provide a vaginal applicator or a pre-fill vaginal applicator. Appellant does believe that he is apparently the first person to be able to prevent the reuse of a vaginal applicator or a pre-fill applicator by utilizing a structure or design which prevents the flexible piston from being removed from the barrel of the applicator either by pulling the plunger outwardly from the barrel after the medication has been dispensed or pushing the piston forwardly after the medication has been dispensed from the applicator.

The Examiner stated in his final rejection that the plunger and piston could be made in two separate pieces and Appellant does not disagree with that contention since it is believed that such structures have been previously provided, although none of the prior art cited by the Examiner apparently discloses such a two-piece structure. However, there is absolutely no suggestion whatsoever in Ferrer that even if the piston and plunger were made as separate components, that the piston would remain in the barrel of the applicator upon the plunger being removed from the applicator. Such a feature is the heart and soul of Appellant's invention. The unique relationship of the barrel, piston and plunger ensures that the plunger will disconnect from the piston if the plunger is moved outwardly from the barrel upon the medication

1 being dispensed from the applicator. Further, the piston in Appellant's structure will  
5 rupture if an attempt is made to push the piston through the dispensing end of the  
10 applicator.

There is not even the most remote suggestion in Ferrer that such a feature or  
5 features as described in the claims under appeal that the plunger will separate from  
the piston as claimed or that the plunger will rupture the piston as claimed.

Appellant contends that the Examiner has failed to consider the claimed  
invention and the prior art "as a whole." MPEP § 2141.02. In determining the  
10 difference between the prior art and the claims, the question under 35 U.S.C. § 103 is  
not whether the differences themselves would have been obvious, but whether the  
claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip  
15 Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983). A prior art reference must be  
considered in its entirety, i.e., as a whole, including portions that would lead away  
from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d  
20 1540, 220 USPQ 303 (Fed. Cir. 1983).

The mere fact that a reference can be modified does not render the resultant  
structure obvious unless the prior art also suggests the desirability of the  
20 modification. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A  
statement that modifications of the prior art to meet the claimed invention would have  
been well within the ordinary skill of the art at the time that the claimed invention was  
made is not sufficient to establish a *prima facie* case of obviousness without some  
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objective reason to modify the references. Ex parte Levingood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

It is therefore suggested that the Examiner's modification of Ferrer in an attempt to render Appellant's structure obvious as claimed fails completely. The problem of reuse of applicators has existed for many years, but now the Examiner suddenly believes that the Appellant's solution to the problem would have been obvious under 35 U.S.C. § 103(a) even though the prior art is completely silent as to any teachings even remotely similar to that claimed in the claims under appeal.

It is therefore submitted that the claims under appeal, and each of them, are patentable. The Ferrer reference does not make independent claims 1 and 8 obvious nor does Ferrer make dependent claims 2 and 3 and dependent claims 10 and 11 obvious.

As stated, claim 2 is dependent from claim 1 and further adds limitations thereto. It is believed that claim 2 is not made obvious under Ferrer under 35 U.S.C. § 103(a) inasmuch as claim 2 depends from an allowable claim.

Claim 3 is also believed to be independently allowable inasmuch as claim 3 specifically describes that the piston is constructed so as to destruct if an attempt is made to manually move the piston towards the open end of the barrel by applying force against the first end thereof as stated in the arguments above.

Claim 10 is believed to be separately allowable for the reasons expressed in support of claims 2 and 8 above.

1           Claim 11 is believed to be separately allowable for the reasons expressed in  
support of claim 3 above.

Accordingly, the Board is requested to allow claims 1, 2, 3, 8, 10 and 11  
inasmuch as it is believed that each claim is not made obvious under Ferrer under 35  
5 U.S.C. § 103(a).

Respectfully submitted,



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15           CERTIFICATE OF MAILING

I hereby certify that the original of APPELLANT'S THIRD AMENDED APPEAL  
BRIEF for TROY M. JUST, Serial No. 10/668,785, was mailed by first class mail,  
postage prepaid, to the Mail Stop Appeal Briefs-Patent, Commissioner for Patents,  
P.O. Box 1450, Alexandria, VA 22313-1450 on this 11<sup>th</sup> day of January, 2007.



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20           DENNIS L. THOMTE